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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/552,422

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Vinod Chintamani Malshe

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EXAMINER

HELM, CARALYNNE E

ART UNIT

PAPER NUMBER

1615

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/552,422	Applicant(s) MALSHE ET AL.	
	Examiner CARALYNNE HELM	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-8 and 10-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-8, and 10-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/16/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

An English equivalent was listed for FR 2787730 in the International Search Report submitted for the PCT from which the instant application claims priority; therefore this reference has been considered. An annotated version of the IDS filed August 16, 2007 is included with this Office action noting this consideration.

Claim Objections

Claim 18 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. This claim appears to add polyethylene sebacate to a composition that already includes this component and therefore does not further limit its parent claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 6-8, and 10-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites that "said pharmaceutical is in the form of different drug delivery systems" then goes on to recite that these "drug delivery systems comprise one or more of" a listing of possible structures. It is not clear if the composition must include multiple structures as is implied by the recitation "different drug delivery systems", or if only one structure is required as implied by the recitation "one or more of." For the sake of application of prior art, the presence of one recited structure is interpreted to meet the limitation drawn to the "different drug delivery systems." Claims 2-4, 6-8, and 10-18 are also indefinite because they require all the limitations of this indefinite independent claim and do not provide additional clarity.

The phrase "particularly" renders claim 18 indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of *Graham v. John Deere Co.* have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 6, 11, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Penhasi (previously cited) in view of Farachi et al (previously cited), Zhu et al. (previously cited), and Jadhav (US Patent No. 6,368,346).

Penhasi teaches a stent composed of a blend of elastomeric and non-elastomeric polymers along with a drug (see paragraph 22-24; instant claim 1). Specifically Penhasi teaches the drug being incorporated in a polymer matrix where, polyethylene sebacate is taught as one of the non-elastomeric polymers (paragraph 35 line 33-34; instant claims 1 and 2). Anti-restenotic drugs are envisioned in the polymer blend and are well known to include anti-inflammatories, anti-proliferatives, anti-coagulants, as well as anti-platelets (see paragraph 46; instant claim 3). In addition to stent forms, Penhasi also teaches film forms of the polymer blends (see examples). Since drugs are envisioned in the invention in general, it would have been obvious to incorporate a drug in a film form of a blend that includes polyethylene sebacate (see instant claims 1 and 11). Although structural components of the stent are composed of the polymer and drug mixture, Penhasi does not teach that the stent (implant) is molded (see paragraph 53). In addition, Penhasi does not explicitly teach the molecular weight of the polyethylene sebacate.

Farachi et al. teach that the polyalkylene sebacates of their invention are particularly good for their mechanical strength, desirable molecular weights, and degradability (see column 2 lines 41-47 and 63-65; instant claim 2). Farachi et al. also exemplify polyethylene sebacate as a particular polyalkylene sebacate (see column 4 lines 57-59; instant claim 2).

Zhu et al. teach that aliphatic polyesters are preferred among biodegradable polymers due to their better biodegradability properties and that this property depends upon their molecular weight (see paragraph 1 lines 5-8; instant claim 2). In addition, Zhu

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et al. also teach molecular weights that range from approximately 800 to approximately 20400 for degradable aliphatic polyesters (see tables 1 and 2).

Jadhav et al. teach a polymeric stent that is taught to be molded into the desired shape (see abstract; instant claims 1 and 6).

Thus in view of teachings of Zhu et al. and Farachi et al., it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a polyethylene sebacate with a molecular weight between 800 and 20,400 along with a drug in the stent of Penhasi. Further such polymeric stents were known to be molded into final form, it also would have been obvious to utilize this avenue to achieve the desired stent shape (e.g. molded implant). Therefore claims 1-3, 6, and 11 are obvious over Penhasi in view of Farachi, Zhu et al., and Jadhav.

Claims 1, 3-4, 8, 10, 12-15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burns et al. (US PGPub No. 2003/0211035).

Burns et al. teach microspheres composed of polymers that are envisioned for biomedical applications (see abstract). The particles are sized from 0.5 microns to 20 microns, can be interpreted as microparticles, and envisioned for controlled (sustained) release (see paragraphs 18 and 32; instant claims 12 and 15). Particles of this size would be capable of being injected and can be administered parenterally, transdermally, orally, and nasally(mucosal) (see paragraph 94; instant claims 8 and 17). Polyethylene sebacate is taught as a polymer contemplated in the particles (see paragraph 34; instant claim 1). Polyoxyethylene ethers (stabilizing agents) are added as to the

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particles to aid in their preparation via emulsion (see paragraph 56; instant claims 13-14). “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.’ In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)....The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., In re Garnero, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)” (see MPEP 2113). Therefore when no structure is implied, the product-by-process recitation does not add any limitations that affect patentability. The product-by-process recited by instant claims 13-14 only adds the stabilizing agents as a structural element and Burns et al. meet this limitation. Burns et al. go on to teach that bioactive agents included in the particles are present at 0.5% to 65% (see paragraph 39; instant claim 4). Particular bioactive agents contemplated include steroids, analgesics, anti-histamines (anti-allergic agents), and anti-cancer agents (see paragraph 89; instant claim 3). Additionally, Burns et al. teach that the particles can be incorporated within a gel (see paragraph 93; instant claim 10). Although the instant intended use is not explicitly envisioned, a recitation of the intended use of the claimed invention must

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result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The gel suspended microparticles of Burns et al. would be capable of being administered to a periodontal space. As explicitly taught elements in the invention of Burns et al., it would have been obvious to one of ordinary skill in the art at the time of the invention to follow their teachings and utilize polyethylene sebacate in their taught bioactive containing microparticles. Therefore claims 1, 3-4, 8, 10, 12-15 and 17 are obvious over Burns et al.

Claims 1 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burns et al. as applied to claims 1, 3-4, 8, 10, 12-15 and 17 above, and further in view of Yoshioka et al. (Journal of Controlled Release 1991 16:341-348) and Hoshino et al. (Biodegradation 2002 13:141-147).

Burns et al. make obvious microparticles composed of the linear aliphatic polyester, polyethylene sebacate, and a drug that are envisioned for controlled release of the drug (see instant claim 1). Burns et al. do not explicitly teach the presence of a lipase in the microparticles.

Yoshioka et al. teach the inclusion of an agent in a polymeric drug delivery system to hydrolyze the polymer and allow control of the degradation rate of the polymer and subsequent rate of drug release (see page 341 column 1-page 342 column 1 line 9 and page 346 column 2 paragraph 2).

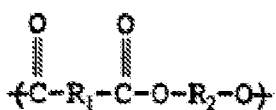
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Hoshino et al. teach that lipases were known to degrade a linear aliphatic polyester of the same form as the polyethylene sebacate taught by Burns et al. (e.g. polybutylene succinate).

Since Burns et al. sought to provide controlled release from their microparticles and the incorporation of a degradation inducing agent in polymeric drug delivery systems was known to aid in controlling the release of drug, it would have been obvious to one of ordinary skill in the art at the time of the invention to include such a compound in the microparticles of Burns et al. Given that Hoshino et al. teach lipases as a degradation inducing agent for linear aliphatic polyesters of the same form as polyethylene sebacate, it would also have been obvious for this artisan to select a lipase to include in the microparticles of Burns et al. and this addition would have had a reasonable expectation of success. Therefore claims 1 and 16 are obvious over Burns et al. in view of Yoshioka et al. and Hoshino et al.

Claims 1 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duan et al. (WO 94/21228 – see IDS) in view of Farachi et al.

Duan et al. teach a composition composed of particulate (granule) drug, a dispersing agent that is a compound comprising a chain of diol/diacid condensate and a propellant (see page 3 lines 1-8; instant claim 1). The dispersant compound is taught to have the form



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where R_1 and R_2 are organic moieties arising from the diacid and diol, respectively (see page 3 lines 13-22). The chain of diol/diacid condensate is taught to be made from any straight chain dicarboxylic acid and dihydric alcohol, where polyethylene glycol is envisioned as such an alcohol (see page 4 lines 7-8, 22, and 28; instant claim 1). Duan et al. go on to teach that the particulate drug can be coated with the dispersant (see page 14 lines 24-29). Duan et al. do not explicitly teach sebacic acid as the diacid.

Farachi et al. teach degradable aliphatic polyesters (see abstract). Specifically, polyalkylene sebacates are taught as particularly good for their degradability (see column 2 lines 41-47 and 63-65; instant claim 2). Farachi et al. also exemplify polyethylene sebacate as a particular polyalkylene sebacate known at the time of the invention (see column 4 lines 57-59; instant claim 2).

Since polyethylene sebacate was already known at the time of the invention and Duan et al. teach diol/diacid condensates prepared from any straight chain diacid and dihydric polyethylene glycol, it would have been obvious to one of ordinary skill in the art at the time of the invention to use polyethylene sebacate as the diol/diacid condensate coating the particulate drug of Duan et al. “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.’ In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)....The structure implied by the process steps should be considered

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when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)" (see MPEP 2113). Therefore when no structure is implied, the product-by-process recitation does not add any limitations that affect patentability. Instant claim 7 recites a product-by-process that does not add structure to the product since no details regarding the coating on the granule is disclosed in the product; therefore, the coated product of Duan et al. in view of Farachi et al. meets its limitations. Thus claims 1 and 7 are obvious over Duan et al. in view of Farachi et al.

Response to Arguments

Applicant's arguments filed November 5, 2009 have been considered but are moot in view of the new ground(s) of rejection necessitated by the amendment.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The rejections and/or objections detailed above are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Friday 9-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/S. TRAN/
Primary Examiner, Art Unit 1615